Bioethics

The Intersection of Bioethics and Health Information Technology

Bioethics Defined

Ethics is a philosophical discipline pertaining to notions of good and bad, right and wrong—our moral life in community. Bioethics is the application of ethics to the field of medicine and healthcare. Ethicists and bioethicists ask relevant questions over providing sure and certain answers.

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MiHIN & Bioethics

An increased focus on the social and ethical issues in health care, science, and technology.

Informs:

- **What information we collect**
- **How we collect the information**
- **How we share information**
- **Unconscious bias in health IT**

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AGENDA

01 Introductions

02 *Proposed Consumer Privacy Framework for Healthcare Data* by Alice Leiter

03 *Health Equity & Ethics in Technology* by Hema Karunakaram

04 Panel Discussion and Questions

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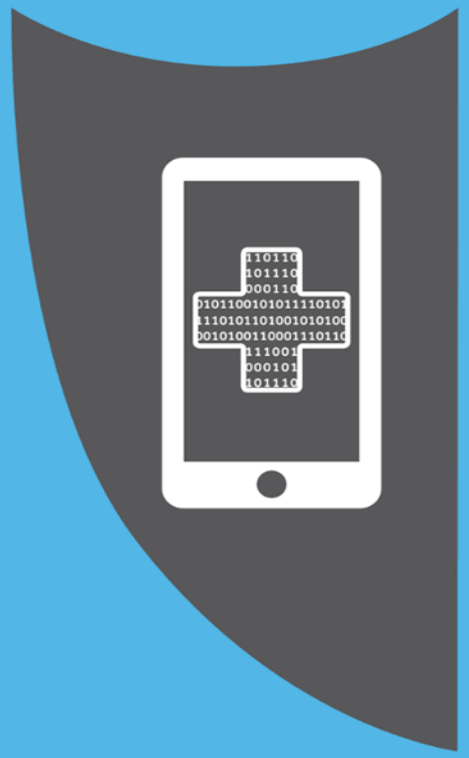
Alice Leiter

Alice Leiter is Vice President and Senior Counsel at the eHealth Initiative, where she leads the organization's privacy work. She is a health regulatory lawyer with a specialty in health information privacy law and policy and spent the bulk of her career in practice at the law firm Hogan Lovells, where she also worked with clients on Medicare and Medicaid pricing and reimbursement.

Alice also spent several years as policy counsel at two different non-profit organizations, the National Partnership for Women & Families and the Center for Democracy & Technology. She currently sits on the DC HIE Policy Board, as well as the boards of Beauvoir School, Educare DC, and DC Greens, the latter of which she chairs. She received her B.A. in human biology from Stanford University and her J.D. from the Georgetown University Law Center. Alice and her husband, Michael, live in Washington, D.C. with their four children.



Proposed Consumer Privacy FRAME-WORK for Health Data

FEBRUARY 2021

CENTER FOR DEMOCRACY & TECHNOLOGY

eHEALTH INITIATIVE

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Project Overview

- Funded by the Robert Wood Johnson Foundation
- Set out to examine the gaps in protection for consumer health information and propose solutions
- Meant to support rather than replace the need for new comprehensive federal data privacy legislation
- Convened Steering Committee made up of experts and leaders representing healthcare, technology, academia, consumers and patients, civil rights organizations, and privacy organizations.
- Through regular workgroup meetings, developed a draft that was publicly released in August
- 30-day public comment period drew several dozen comments
- Final framework released in February

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Why Was This Project Necessary?

- HIPAA covers protected health information when held by providers, payers and their business associates (contractors)
- HIPAA does NOT cover data once it leaves the traditional healthcare system
- HIPAA does NOT protect data held by an individual or uploaded onto most tech platforms (apps, wearable devices, web browsers)
- Result: vast amount of under-protected health information
  - FTC Act not designed to protect this universe of data
  - State laws are patchy and sometimes conflicting
  - Data often subject simply to companies' terms of service, which tend to be dense, lengthy and rarely read or understood
- Codes of Conduct and sets of industry best-practices do not go far enough

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Why Was This Project Necessary?

- New CMS and ONC final regulations will increase amount of health data flowing from health system to individuals
  - HIEs will play a patient access role unlike that which many have played before
- Proposed HIPAA rule aims to increase information sharing with broader array of care-givers without individual consent
- COVID-19 pandemic has illustrated challenges, including consumer trust, associated with widespread collection and use of health data; shone spotlight on disparities with respect to information use
- Pre-election momentum on Capitol Hill for new federal data privacy legislation; post-election momentum building, particularly in relation to COVID-19

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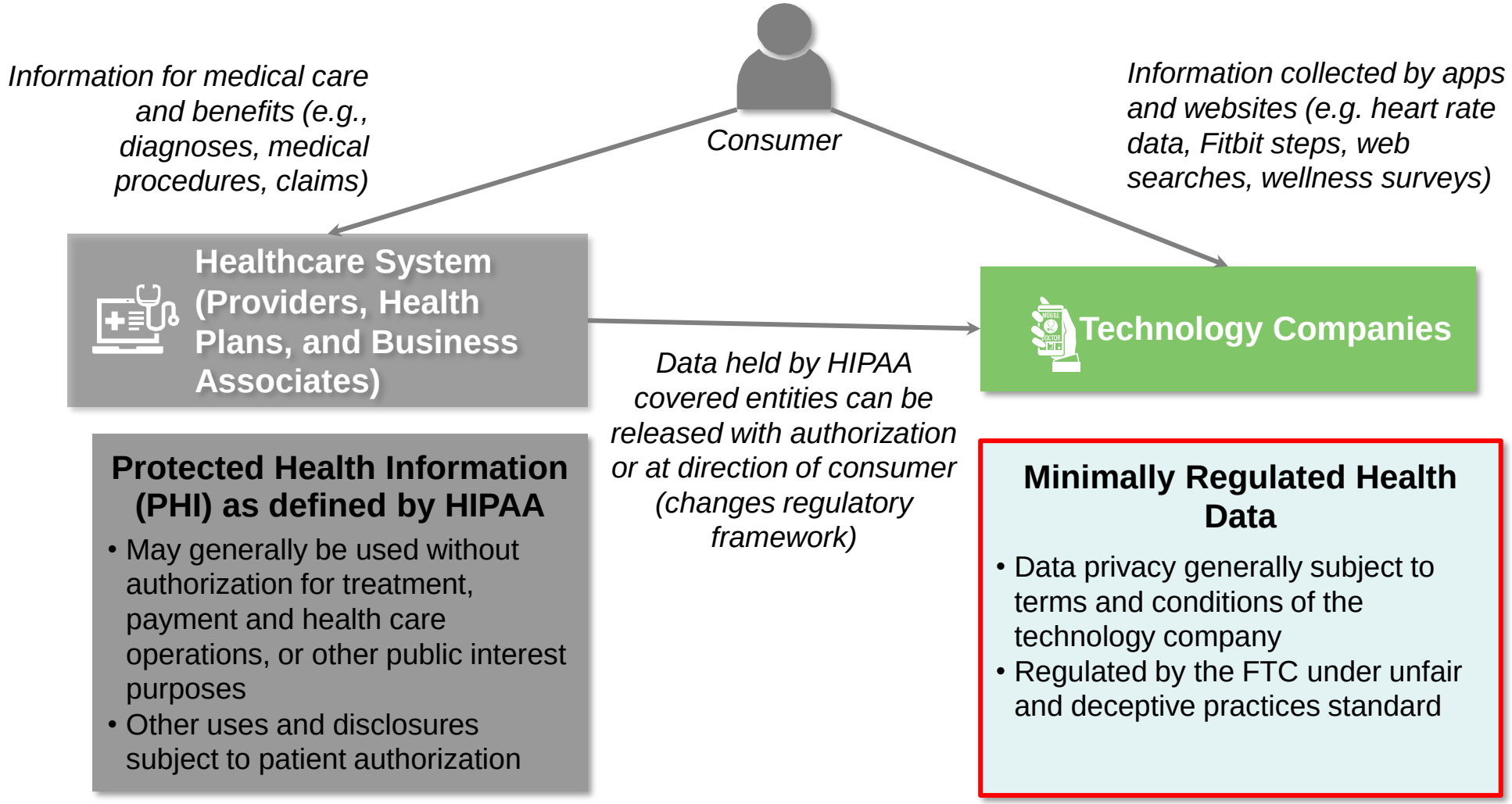
Universe of Data our Project Addresses



NOT in scope for discussion:

- **De-identified health information:** Patient health information from a medical record that has been stripped of all "direct identifiers" for a particular individual
- **Excluded identifiable health information:** Employment records containing health information; educational records containing health information (subject to FERPA); patients' personal health records that are not available to anyone else

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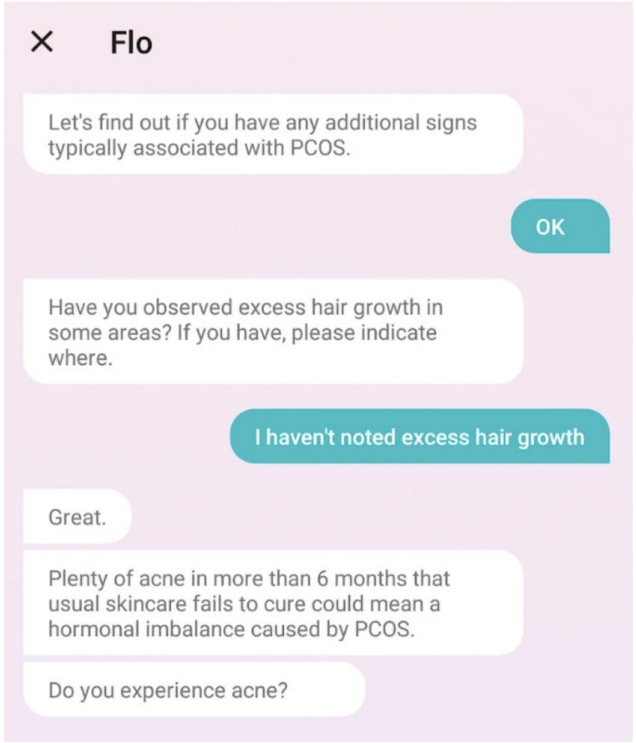
Harms That May Come from a Privacy Violation

- Embarrassment
- Creep into other areas of life: employment, education, etc.
- Inaccurate data
- Discriminatory health treatment
- Lack of autonomy
- Lack of trust in technology/health services

The New York Times

Flo Settles FTC Charges of Misleading Users on Privacy

Jan. 13, 2021
By Natasha Singer



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Value Proposition of Framework

- Bridge to future federal legislation, not a be-all, end-all solution
- Raises the bar for consumer privacy
- Benefits companies and organizations that collect and use health data
- Aids regulators and oversight bodies

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Framework Substance Definition

We embraced a broad definition of “consumer health information” based on purpose and use of data.

- No gaps in coverage - wrap around protection for consumers regardless of format or entity who holds it.
- Reflects modern data practices which are complex, opaque, and instantaneous.
- Tech neutral and evolves with time.

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Substance Proposal
Data Collection and Use

This section is intended to categorically prohibit secondary uses of health data that consumers do not ask for or expect.

- Limits the amount of consumer health information collected, disclosed, or used to only what is necessary to provide the product or feature the consumer has requested.
- Data collection, sharing, and use limits carry through to third parties.
- Predicated on clear notice and affirmative consent process.

This approach is more stringent than other voluntary frameworks or legal standards, but we believe health data warrants the protection.

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Substance Proposal Exceptions

The framework includes limited exceptions for:

- Research
- Emergency Use
- Security and Product Functionality
- Employee Information
- Limited Commercial Purposes

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Structure: Self-Regulatory Program

- Consortium of healthcare and health-tech leaders forms a self-regulatory body that operates independently from, but in alignment with, the FTC
  - Program is housed in and run by a to-be-selected existing independent organization with experience standing up and running self-regulatory bodies
  - Enforcement handled by the consortium but backstopped by the FTC
  - Voluntary self-certification to hold member companies to the Framework's standards
- Individual companies accepted as members
  - Thorough education and onboarding review at enrollment
- Requires public commitment

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Accountability Mechanisms

- Annual assessments and audits/reviews; active “spot-check” monitoring on a random sample of members throughout each year
- Independent monitoring by program staff or other authorized evaluators, including publicly announced cases
- Active complaint-gathering process;
- Dispute resolution mechanism for resolving consumer complaints or complaints by another company based on the program’s standards;
- Requirement to develop a corrective action plan (CAP) and process to lose certification if CAP fails;
- Penalties for persistent or willful non-compliance with the law and/or the program’s standards, such as suspension or dismissal from the program, and/or referral to the FTC and/or state AG;
- Possibility of FTC and/or state AG enforcement of violation of agreed-to industry standards

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Phase 2 Context and Goals

- The pandemic has placed even greater focus on health data and how it is collected, disclosed, and used
- Priorities for a next phase of work would include:
  (1) Advocating for and refining our framework, including further engagement of consumers and consumer groups – particularly those representing vulnerable and under-served communities
  (2) Advancing the framework from a proposal into a more fully developed self-regulatory initiative, including selection of a group to house it and recruitment of individual members; and
  (3) Exploring in detail the ways in which the framework's standards and the program's design should and can address inequities in the use of consumers' health-related information.

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Hema Karunakaram

Hema Karunakaram is the Program Manager for Health Equity at IBM Watson Health. Hema coordinates research and evaluation of healthcare analytics & AI through a public health lens and supports product strategy across IBM's healthcare and life sciences assets. Her areas of focus include incorporating health equity metrics into analytic models for payers and government entities, and identifying and mitigating potential sources of bias in product design. Her team's work advocating for increased collection and analysis of race & ethnicity data by employer-sponsored health plans was recently published in Health Affairs.

Hema currently serves on the Board of Directors for the South Asian Public Health Association. She has a Master's in Public Health from Dartmouth College and a Bachelor's in Environmental Engineering from the University of Michigan, and is based in Chicago, IL.

Health Equity & Ethics in Technology

Hema Karunakaram, MPH
Program Manager, Health Equity
IBM Watson Health & IBM Corporation

IBM Watson Health / © 2021 IBM Corporation

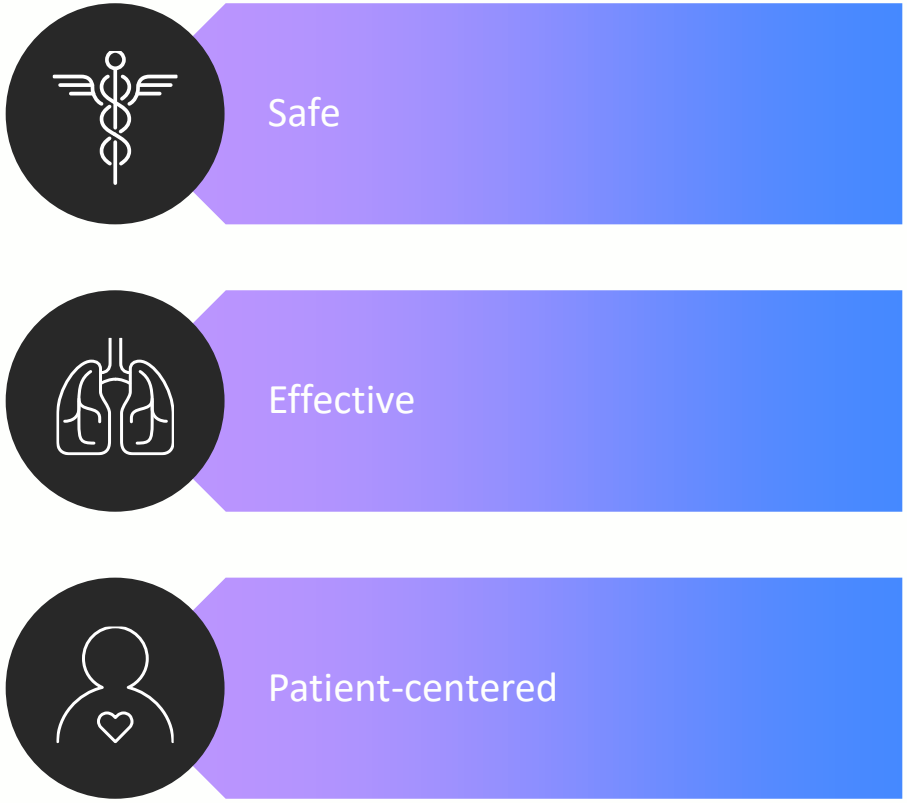
What is health equity?

In the first image, it is assumed that everyone will benefit from the same supports. They are being treated equally.

In the second image, individuals are given different supports to make it possible for them to have equal access to the game. They are being treated equitably.

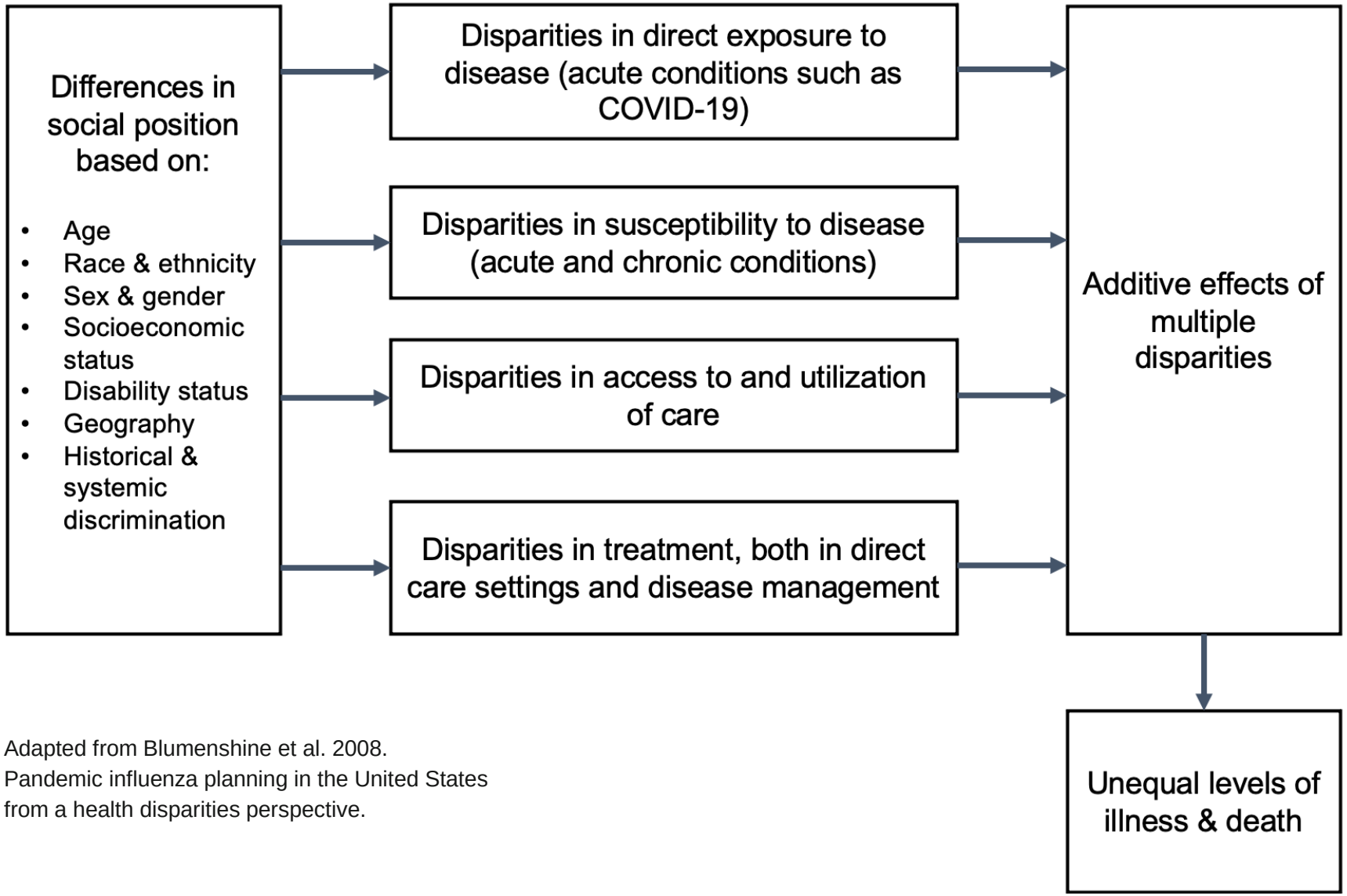
In the third image, all three can see the game without any supports or accommodations because the cause of the inequity was addressed. The systemic barrier has been removed.

Six Aims for Quality Improvement in Healthcare



Crossing the Quality Chasm: A New Health System for the 21st Century. Committee on Quality of Health Care in America, Institute of Medicine. National Academies Press; 2001

Where do health disparities come from?



Adapted from Blumenshine et al. 2008.
Pandemic influenza planning in the United States from a health disparities perspective.

Racial and Ethnic Disparities in Health Among Employees at Large Firms

| Henke RM et al. *J Occup Environ Med.* 2015;57(6):627-634.

Study examined IBM® MarketScan® Commercial claims data to determine if there were racial and ethnic disparities in the prevalence of 15 chronic health conditions across 1,4341,727 employees from 46 large US employers.

Significant differences were identified in disease prevalence across the following racial and ethnic categories:

- Blacks (23.5%) had a significantly higher adjusted prevalence for **hypertension** than other race/ethnic categories
- Whites (5.0%) and Native Americans (4.9%) had significantly higher prevalence of **depression** than Blacks (2.5%) and Asians (1.5%)
- Native Americans (0.7%) and Whites (0.6%) had a significantly higher prevalence of **COPD** than Hispanics (0.3%) and Asians (0.3%), but no difference in prevalence compared with the other groups
- Asians had a significantly lower adjusted average number of chronic conditions (0.46%) compared to the other race and ethnic groups
- Native Americans (7 out of 15) and Blacks (6 out of 15) had significantly higher prevalence for the conditions studied compared to other study groups

These insights can provide guidance for employee wellness program development and caution against discrimination against groups with higher condition prevalence. Monitoring and addressing health disparities among employees requires collection and analysis of characteristics including race & ethnicity, job level, and location, among other factors.

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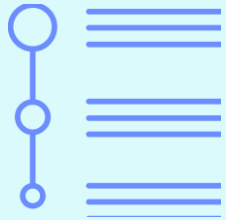
Challenges to collecting and using race & ethnicity data

Race & ethnicity and other SDOH data is often **incomplete**, **inaccurate**, or **inaccessible** in EHRs and claims.

Lack of standardized reporting, despite OMB standards for race & ethnicity fields



Privacy concerns and fear of data misuse

Variability in method of data collection: patient-reported vs. imputed or observed

Data is not considered actionable even when available

Institutional commitment is required to improve data collection

BCBS of Massachusetts is expanding their health equity strategy by:

- Inviting members to update race, ethnicity, and language data in member portal
- Creating a health equity advisory council to regularly review gaps in care and create benchmarks for improvement

That approach is vital to creating an equitable system, health policy experts recently wrote in Health Affairs.

"A commitment to racial equity and social justice includes transparently collecting and reporting demographic data, identifying disparities, understanding population needs, and tailoring interventions to close gaps in care," wrote Bruce W. Sherman, Irene Dankwa-Mullan, Hema Karunakaram, Leah Kamin, Tiffani J. Bright and Kyu Rhee. "Ultimately, for organizations to identify and eliminate gaps in their programs, ensure equitable quality care, and address health disparities, the collection of employee health data by race and ethnicity must be improved."

MAR 9, 2021

A call to action

RACHEL COPPOLA

Leading researchers call for hard data on health inequities, as Blue Cross embarks on ambitious new initiative

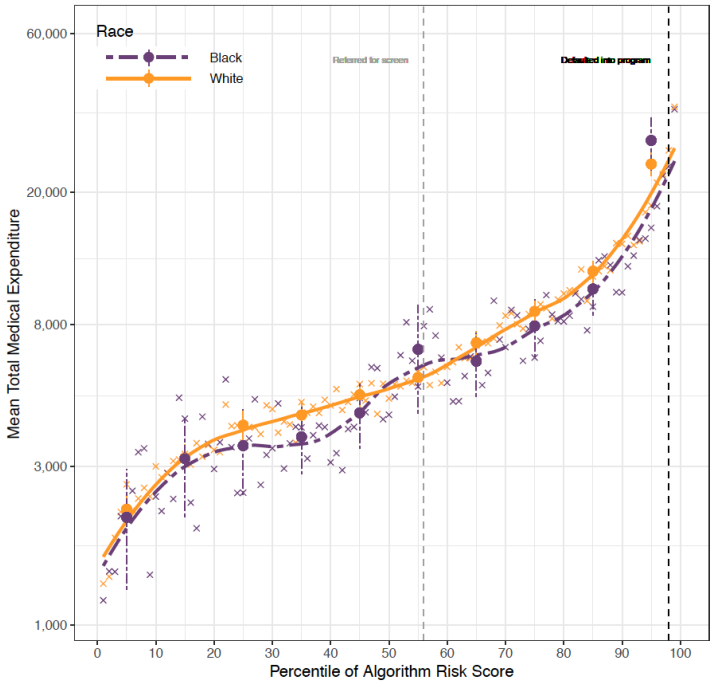
RACHEL COPPOLA | NEWS SERVICE OF BLUE CROSS BLUE SHIELD OF MASSACHUSETTS

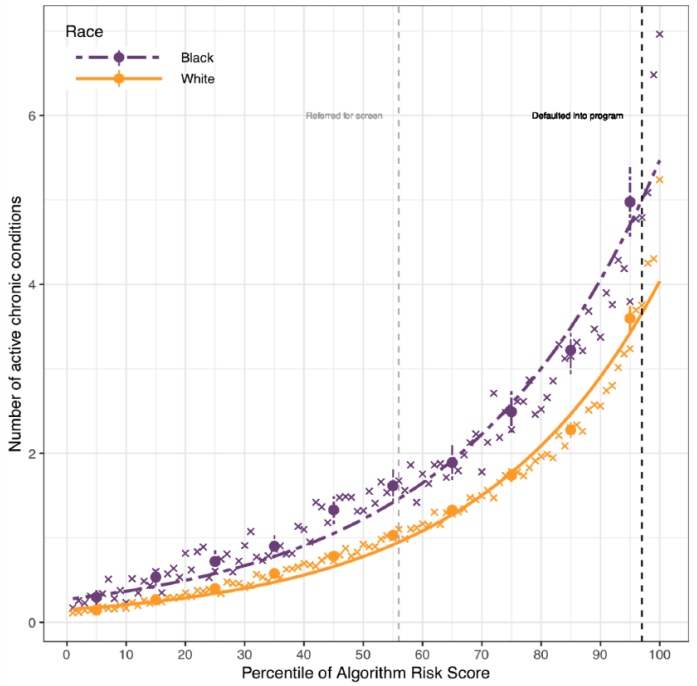
Risk of bias in health data models

RESEARCH ARTICLE

Dissecting racial bias in an algorithm used to manage the health of populations

Ziad Obermeyer[1,2,*], Brian Powers[3], Christine Vogeli[4], Sendhil Mullainathan[5,*,†]





- Algorithm used health costs as a proxy for health needs
- Black patients with poorer health were shown to have same risk score as white patients with better health
- Models incorporating race & ethnicity should assess underlying racial disparities and incorporate additional variables

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Overcoming bias through data integration

- Underreporting of key social determinants can mask gaps in access and treatment, *but…*
- Overreliance on any single variable (such as race) can lead to misallocation of resources
- Organizations and agencies should strive to cover gaps in their own data *AND* supplement their analytics with additional data sources to gain a more holistic understanding of patients

Generalization based on limited data:

Black patients aren't getting vaccines because of mistrust.

Nuanced understanding based on integrated data sources:

Many Black patients do have hesitancy and mistrust related to vaccines; many also face challenges related to access, that may be mediated by geography, transportation, internet use, whether they have a PCP, and other social factors.

Applying National Survey Data and Market Segmentation Model to Claims Data to Uncover Opportunities of Impact in Vulnerable Populations

| Hodor B et al. NACCHO 360 Virtual Conference 2020.

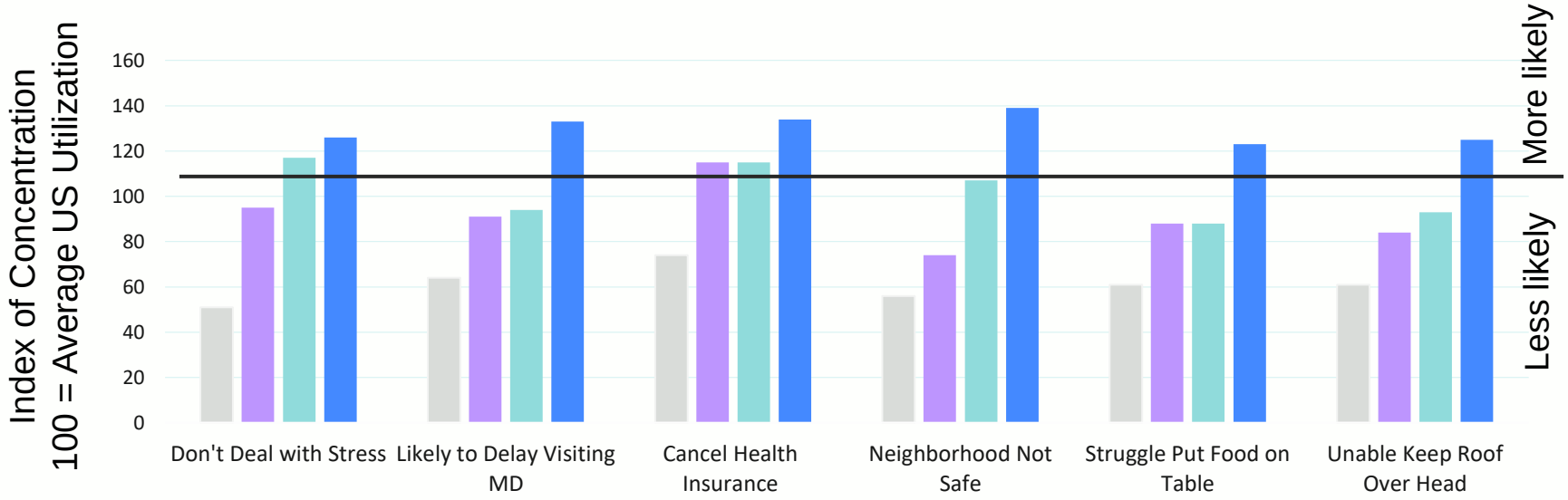
High emergency department (ED) use often indicates poor access to primary care and preventive services. This study examined the association between lifestyle and health-seeking behaviors and ED utilization.

External claims data for **22,443** Medicare Advantage patients linked to:

- IBM Watson Health PULSE™ Healthcare Survey
- Claritas PRIZM® Premier Segmentation

Household Education and ED Visits (per 1000 member months*)

Graduate Plus	College Graduate	Some College	High School
n = 3,717	n = 5,461	n = 6,721	n = 6,544
560.49 ED Visits	615.159 ED Visits*	615.33 ED Visits*	706.74 ED Visits*



Combining claims data with national healthcare survey and market segmentation data uncovered sociodemographic and behavioral insights not generally available from claims data alone. These analyses can identify potential opportunities for intervention in vulnerable populations.

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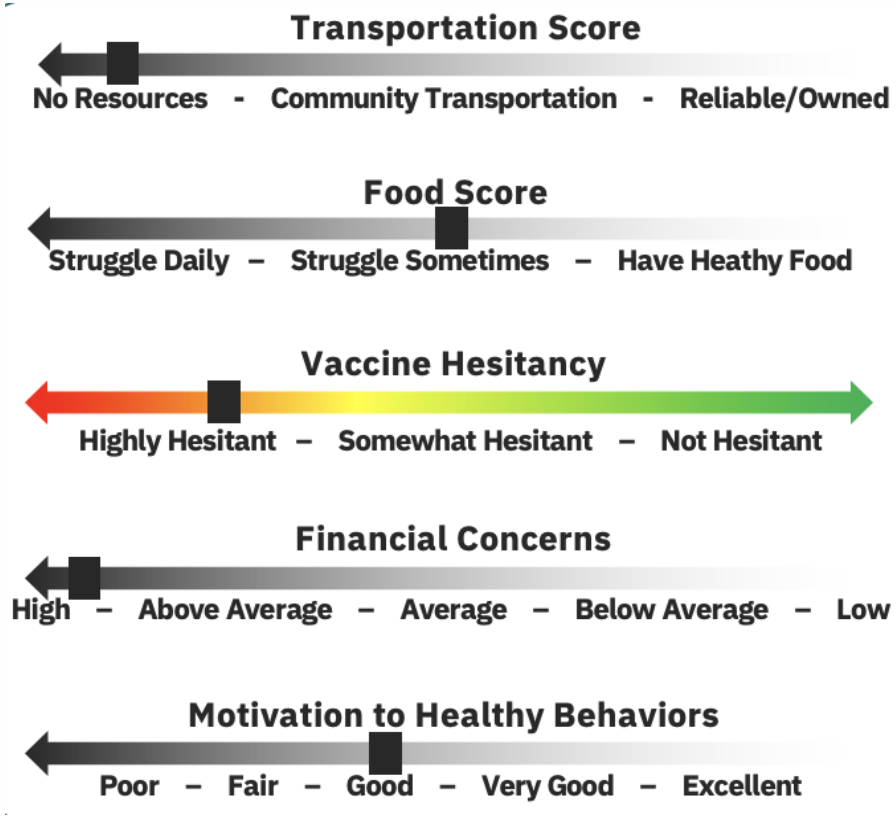
Creating a Motivational Index by combining data sources

Machine learning & AI



Key Takeaways

1. Collecting **SDoH data, including race & ethnicity**, is essential to addressing disparities in access and care
2. Models that rely on incomplete or inaccurate data can be **biased or unethical**
3. **Integrating diverse sources of data** across agencies and institutions leads to a more nuanced understanding of patient needs

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